DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 9, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-04

Tom Waterer, President
SeaCrest Foods, Inc.
3407 East Marginal Way South
Seattle, Washington 98134

WARNING LETTER

Dear Mr. Waterer

We inspected your firm located at 3407 East Marginal Way South, Seattle, Washington, on June 12, 13, and 15, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to George Kaayk at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your hot smoked fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for hot smoked vacuum packaged salmon does not list the monitoring procedure or frequency at the cold storage critical control point to control the food safety hazard of *Clostridium botulinum* toxin formation during finished product storage.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for hot smoked vacuum packaged salmon at the cold storage critical control point to control *Clostridium botulinum* toxin formation is not appropriate. Your corrective action lists only the repair of the cooler, the cause of the deviation. An appropriate corrective action must also include steps to ensure that potentially unsafe product does not enter commerce (i.e., holding and analytically testing the affected product).

3. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limits of [redacted] hours, [redacted] degrees Salinity, [redacted] Brine to Fish ratio, and [redacted] inches thickness for Hot Smoked Salmon at the Brining critical control point to control *Clostridium botulinum*. The example provided in the Fish & Fishery Products Hazards & Control Guide, including the statement that the critical limits are designed to produce a minimum water phase salt level of 3.5%, is for illustrative purposes only. The adequacy of **your** process should be established by a scientific study and your validated process verified by finished product sampling a minimum of once every three months. Another option is to establish a safe critical limit for your water phase salt levels (3.5%) and conduct lot-by-lot testing of your product as part of your monitoring procedures.

4. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control *Clostridium botulinum* at the Brining critical control point. Your "Daily Brine, Salt, & Temperature Check" for dates 4/30/00 through 5/31/00 show consistent salinity checks of [redacted] to [redacted] degrees for each day of production. Your critical limit is [redacted] degrees. Your statements to our investigator indicate that you did not consider [redacted] to [redacted] degrees salinity unacceptable even though it did not meet your critical limit.

5. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of checking the brine to fish ratio ([redacted]) and monitoring the thickness to the fish pieces ([redacted] inches) at the Brining critical control point to control *Clostridium botulinum*. In addition, your firm did not follow the monitoring procedure/frequency of checking the cooler temperature hourly at the Vacuum Packaging critical control point to control *Clostridium botulinum*. Your Daily Cooler Temperature Check shows only three checks per day

6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor five of the eight areas of sanitation sufficiently to ensure control as evidenced by the following:

   - Water Safety - No backflow protection device on the water lines used to fill brine tanks.

   - Employee Practices - Dirty gloves and aprons; Raw and cooked product stored in close proximity in the cooler; Lack of effective hair restraints.

   - Handwashing - No soap in restroom; Sink in processing area unavailable for handwashing use.

- Protection from Adulterants - Automotive supplies and paint thinner stored in close proximity to packaging area.

- Pest Control - Flies in processing area.

Your records indicated that sanitation conditions and practices were acceptable during your 6:00 am, 12:30 pm, and 3:00 pm sanitation inspections on June 13, 2000. Our investigators cited numerous deficiencies on their Form FDA 483, based on their observations on that same day. None of the observations recorded on the FDA 483 were documented on your sanitation audit for that day.

Labeling

Review of your firm's labels for the smoked salmon products, collected during the June 12, 2000 inspection, have found these products to be misbranded under section 403(a)(1) of the Act in that displaying "ALDER SMOKED" on these labels is false and misleading because these products are not smoked using wood, nor are they smoked using alder wood.

The above HACCP and labeling violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 & 403 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA With Disclosure Statement